IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Ksander, G.M., et Art Unit: 1626

al. Examiner: Janet L. Coppins

APPLICATION NO: 10/556,988

FILED: February 3, 2006

FOR: N-ACYL NITROGEN HETEROCYCLES AS LIGANDS OF PEROXISOME PROLIFERATOR-ACTIVATED RECEPTORS

MS: General Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

PETITION REGARDING PATENT TERM ADJUSTMENT UNDER C.F.R. §1.705(b)

Sir:

In accordance with 37 C.F.R. § 1.705(b), Applicant hereby applies for patent term adjustment under 35 U.S.C. § 154(b) of 522 days. This application is being filed with the payment of the issue fee, as required by 37 C.F.R. § 1.705 (b).

I Fee

As required by 37 C.F.R. § 1.705(b)(1), this application is accompanied by a request to charge Deposit Account No. 50-4409 for \$ 200.00 to cover the required fee (as defined in 37 C.F.R. § 1.18(e)). Please charge any deficiencies or any additional fees due in response to this request to Deposit Account 50-4409.

ii. Statement of the Facts involved

A. Correct Patent Term Adjustment

The Notice of Allowance, which was mailed on December 16, 2008, indicated a preliminary Patent Term Adjustment of 518 days.

Patentee has calculated an initial patent term adjustment of 713 days based on the following facts:

Case Law

In Wyeth v. Dudas, 2008 U.S. Dist. LEXIS 76063 (D.D.C. 2008), the District Court of the District of Columbia addressed the United States Patent and Trademark Office (USPTO) interpretation of 35 U.S.C. § 154(b)(2). The Court granted summary judgment in favor of Wyeth, determining that the USPTO misconstrued the first sentence of 35 U.S.C. § 154(b)(2)(A), and as a result, improperly denied Wyeth a portion of patent term to which Wyeth was entitled under 35 U.S.C. § 154.

In the opinion, the Court stated that "the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for 'A delay' or for 'B delay,' whichever is larger, but never A + B." However, Plaintiff Wyeth argued that the § 154(b)(1)(A) and § 154(b)(1)(B) period overlap only if they occur on the same calendar day or days. The Court determined that Wyeth's construction of § 154(b)(2)(B) was correct.

Simply put, the holding of the Court is that the excluded overlap recited in the first sentence of 35 U.S.C. § 154(b)(2)(A) only occurs if a 35 U.S.C. § 154(b)(2)(A) period and a 35 U.S.C. § 154(b)(2)(B) period run concurrently. As such, a patent holder is entitled to recoup the 35 U.S.C. § 154(b)(2)(A) period that falls outside of the 35 U.S.C. § 154(b)(2)(B) period in addition to the 35 U.S.C. § 154(b)(2)(B) period itself.

Relevant Dates

The above identified application has a 35 U.S.C. §371 filing date of February 3, 2006.

The first Office Action, which was a Restriction Requirement, was mailed on March 17, 2008, resulting in a PTO delay of 349 days beyond the 14 months provided by 35 U.S.C. §154(b).

A Response by Patentee was filed April 17, 2008, within the 3 months provided by 35 U.S.C. §154(b).

An Office Action was mailed July 8, 2008, within the 4 months provided by 35 U.S.C. \$154(b).

A Response by Patentee was filed October 8, 2008, within the 3 months provided by 35 U.S.C. §154(b).

A second Office Action was mailed on February 4, 2009, within the 4 months provided by 35 U.S.C. §154(b).

A Response by Patentee was filed June 3, 2009, resulting in a 30 day delay beyond the 3 months provided by 35 U.S.C. §154(b).

A Notice of Allowance was mailed June 24, 2009, within the 4 months provided by 35 U.S.C. §154(b).

The issue fee has been paid on September 24, 2009 in a paper accompanying the instant petition, within the 3 months provided by 35 Ü.S.C. §154(b).

Accordingly, the initial PTO adjustment based on delay under 35 U.S.C. § 154(b)(2)(A) is 349 days. The reduction in term adjustment due to applicant delay is 30 days, resulting in a patent term adjustment of 319 days under 35 U.S.C. § 154(b)(2)(A).

The initial 35 U.S.C. § 154(b)(2)(B) period for the instant application began on February 3, 2009 (three years after the filing date of February 3, 2006) and will end on the date of issuance. The initial 35 U.S.C. § 154(b)(2)(B) period running from February 3, 2009 until payment of the issue fee (September 24, 2009) is 233 days. The reduction in term adjustment due to applicant delay is 30 days, resulting in an initial patent term adjustment of 203 days under 35 U.S.C. § 154(b)(2)(B).

There was 0 days of PTO delay under 35 U.S.C. § 154(b)(2)(A) that occurred within the initial 35 U.S.C. § 154(b)(2)(B) period that should be excluded from the patent term adjustment calculation under the holding of Wyeth v. Dudas.

Accordingly, the sum of the 35 U.S.C. § 154(b)(2)(B) delay (203 days) and non-overlapping 35 U.S.C. § 154(b)(2)(A) delay (319 days) is 522 days.

The initial PTA printed on the Notice of Allowance is only 319 days, which the USPTO is presumed to have calculated using the method considered proper before the holding of Wyeth v. Dudas. Applicants therefore respectfully request reconsideration of the initial PTA calculation.

B. Terminal Disclaimer

The above-identified patent is not subject to a Terminal Disclaimer.

C. Reasonable Efforts

Any applicant delays under 37 C.F.R. § 1.704 are set forth above. There were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing of examination of the above-identified application, as set forth in 37 C.F.R. § 1.704.

Respectfully submitted,

Novartis Institutes for BioMedical Research, Inc. 220 Massachusetts Avenue Cambridge, MA 02139

(617) 871-3105

Date: September 23, 2009

Attorney for Applicant Reg. No. 45,361